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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,857	12/29/2000	Ron J. Doyle	12818.IUSU1	8938

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/02/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/750,857	DOYLE ET AL.
	Examiner	Art Unit
	Khatol S Shahnan-Shah	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 June 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 and 51-57 is/are pending in the application.

4a) Of the above claim(s) 5-7 and 19-21 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4,8-18 and 51-57 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- 1) Certified copies of the priority documents have been received.
- 2) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

1. Applicants' election with out traverse of 3/04/2002, paper # 10 is acknowledged. Applicants elected group I claims 1-21. Newly added claims 51-57 are also drawn to the same invention.
2. Applicants' response to the second election mailed June 6, 2002, paper # 13 is acknowledged. Applicants elected species "polyphenol oxidase", "prokaryote", "gram negative", "extracellular matrix", "catheter", " treats infection in a patient in need thereof" and "E.coli".
3. Currently claims 1-21 and 51-57 are pending. Claims 5, 6, 7, 19, 20 and 21 are withdrawn further from consideration as being drawn to non elected species.
4. Claims 1-4, 8-18 and 51-57 are under consideration.

*Information Disclosure Statement*

5. Information disclosure statement, received 2/02/2001, paper # 7 is acknowledged.

*Priority*

6. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading, "This is a continuation of Application No. 60/173,821, filed 12/30/1999." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

*Specification*

7. The disclosure is objected to because of the following informalities: Specification page 15, line 17, FEMS Microbiology Letters is misspelled.

The use of the trademark Triton X -100 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-4, 8-18 and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what applicants intend in recitation of the phrase “ enzymatically modifying an adhesin on the organisms” in claim 1.

It is not clear what applicants intend in recitation of the phrase “an effective amount of an enzyme” in claim 9.

It is not clear what applicants intend in recitation of the phrase “in the binding site an adhesin ”in claim 12.

Claim 15 recites the limitation "the method of claim 12, wherein a lectin comprises the carbohydrate binding site". There is insufficient antecedent basis for this limitation in the claim.

Claim 12 does not recite carbohydrate binding site.

Claims 52 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for reciting improper Markush group. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being “ selected from the group comprising of A, B, and/or C.” See *ex parte Markush*, 1925 C.d. 126 (Comm'r Pat. 1925).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 51, 53, 54 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyasaki et al. (Journal Dental Research Vol. 67, No.10, PP. 1300-1306,1987). Applicants' IDS already made of record.

Claims are drawn to a method of reducing binding of a microorganism to a surface comprising enzymatically modifying an adhesin on the microorganism.

Miyasaki et al. teach a method of reducing binding of a microorganism to a surface comprising enzymatically modifying an adhesin on the microorganism by exposing the microorganism to an effective amount of an enzyme (see abstract, material and methods, pages 1300- 1301 specially adherence assay). Miyasaki et al teach the organism comprises a prokaryote (Streptococci) (see material and method, page 1300). Miyasaki et al. also teach

extracellular matrix and human fluid (saliva) see page 1301 adherence assay. Miyasaki et al. teach decreasing adhesion (see abstract and page 1302).

10. Claims 9, 10, 17, are rejected under 35 U.S.C. 102(b) as being anticipated by Miyasaki et al. (Journal Dental Research Vol. 67, No.10, PP. 1300-1306,1987). Applicants' IDS already made of record.

Claims are drawn to a method of reducing adhesion by a microorganism, comprising exposing the microorganism to an effective amount of an enzyme which reduces adhesion by the microorganism.

Miyasaki et al. teach a method of reducing adhesion by a microorganism, comprising exposing the microorganism to an effective amount of an enzyme, which reduces adhesion by the microorganism. (see abstract, material and methods, pages 1300- 1301 specially adherence assay). Miyasaki et al. teach the organism comprises a prokaryote (Streptoccoci) (see material and method, page 1300). Miyasaki et al. also teach wherein the enzyme catalyzes a reaction for modifying a molecule on the organism (see page 1304 under discussion, proteolytic activity).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 9-15, 17-18 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen (WO 98/26807) in view of Singh et al. (Carbohydrate Research Vol. 244, PP. 137-147, 1993). Applicants' IDS already made of record.

Claims are drawn to a method of reducing adhesion by a microorganism comprising exposing the microorganism to an effective amount of an enzyme which reduces adhesion by a microorganism.

Johansen teaches a method of reducing adhesion by a microorganism comprising exposing the microorganism to an effective amount of an enzyme which reduces adhesion by a microorganism. (see page 1 and claim 1). Johansen teaches that bacteria have a marked tendency to adhere to a surface and initiate the formation of biofilms (page 1, lines 9-10). Johansen also teaches variety of enzymes reduce adhesion of these bacteria from the surface (see page 2, lines 10-14 and page 4). Johansen teaches microorganisms comprising prokaryotes, gram-negative bacteria and *E.coli* (see page 3, lines 31-36 and claim 10). Johansen teaches that this removal or release (reducing adhesion) of biofilm from the surface takes place by catalytic action of the enzyme. (see page 3, lines 1-2, page 22 (results) and table 1, page 24). Johansen teaches wherein the surface comprises medical devices and implants. (see page 1, lines 10-30, page 2-3 and page 31, lines 5-25). Johansen does not teach modification of a side chain of an amino acid.

However, Singh et al. teach modification of a side chain of an amino acid. (see abstract and materials and methods). Singh et al. teach that the active site of glucan- binding lectin of *Streptococcus sorbinus* was probed by specific amino acid modifying reagents. Singh et al. teach chemical modification of lectins, including lectin adhesins (see page 138). Singh et al. teach

essential amino acid residue such as tyrosine needed for adherence (see abstract). Singh et al. also teach chemical modification of *E. coli* adhesions (see page 146).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the methods taught by Johansen with the methods taught by Singh et al. to obtain the claimed invention.

One having ordinary skill in the art would have been motivated by the teachings of Singh et al. in the essential role of bacterial lectin adhesins in the pathogenesis and growth of bacteria (see pages 137-138 and 146) to develop a method of reducing adhesion by a microorganism comprising exposing the microorganism to an effective amount of an enzyme which reduces adhesion by a microorganism.

### ***Conclusion***

#### **12. No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Art Unit: 1645

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Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

November 27, 2002



MARK NAVARRO  
PRIMARY EXAMINER